FEB - 8 2001

K003496

1 of 2

V 510(K) SUMMARY

Pioneer Surgical Technology

510(K) Notification Summary:
Cannulated Screw System by Pioneer

ADMINISTRATIVE INFORMATION

Manufacturer Identification And Sponsor	Pioneer Surgical Technology 375 River Park Circle Marquette, Michigan 49855-1781 Telephone: (906) 226-9909 Facsimile: (906) 226-9932
Official Contact	Amy H. Mommaerts, Manager Regulatory Affairs
Date Prepared	November 10, 2000

DEVICE IDENTIFICATION

Proprietary Name	Cannulated Screw System by Pioneer
Common Name:	Cannulated Screw
Classification Name And Reference	Screw, Fixation, Bone
Regulation Number	888.3040
Classification Number	87HWC

Proprietary Name	Cannulated Screw System by Pioneer
Common Name: Screw	Washer
Classification Name And Reference: Screw	Washer, Bolt, Nut, Orthopaedic
Regulation Number	888.3030
Classification Number	87HTN

Devices on Which Substantial Equivalence is Claimed

The Cannulated Screw System by Pioneer is predicated on the ZIMMER MAGNA-Fx; the ZIMMER Mini MAGNA-Fx; and the Synthes Cannulated Screw System.

Device Description

The Cannulated Screw System by Pioneer consists of cannulated screws of varying diameters, lengths and thread configurations to accommodate variations in surgical technique and severity level of fracture. The system includes correspondingly sized washers, the use of which is optional. The cannulated screws are self-cutting and self-

tapping in appropriate bone stock, which maximizes OR efficiency. The threads are reverse cutting, facilitating screw removal and decreasing the chance of breakage. These devices are intended for single use and will be offered both sterile and non-sterile.

Intended Use
The Cannulated Screw System by Pioneer will be indicated for use in long and small bone fracture fixation, which may include the following:

1. Fractures of the tarsals and metatarsals;
2. Metatarsal and phalangeal osteotomies;
3. Fractures of the carpals and metacarpals;
4. Carpal and metacarpal arthrodesis;
5. Small fragments of the hand and wrist;
6. Ligament fixation;
7. Sacroiliac joint disruptions;
8. Fractures of the distal femur and proximal tibia;
9. Intracapsular fractures of the hip;
10. Ankle arthrodesis;
11. Pelvis and acetabulum fractures; and
12. Areas where accurate screw placement is vital.

This system is not indicated for use in the spine. The Cannulated Screw System by Pioneer will be offered both sterile and non-sterile and is a single use device.

Technological Characteristic Compared to Predicate Device
The Cannulated Screw system by Pioneer was designed referencing the following ASTM standards, similar to the predicate Zimmer Magna-FX, Mini Magna-FX and Synthes cannulated screws: 1) F 543, *Standard Specification for Metallic Medical Bone Screws;* and 2) F 116, *Standard Specification for Medical Screwdriver Bits*

Performance
Based on the screw material and geometrical equivalence in the proposed system an at least equivalent comparison has been logically derived from the information available.

Performance Data
The Cannulated Screw System by Pioneer is predicated on the use Zimmer Magna-FX and Synthes Cannulated screws. The Cannulated Screw system by Pioneer will be evaluated and compared to the predicate devices with the following ASTM Test standards: 1) F 1691, *Standard Test Method for Determining the Axial Pull-Out Strength of Medical Bone Screws;* 2) F 117, *Standard Test Method for Driving Torque of Medical Bone Screws;* and 3) F 1622, *Standard Test Method for Measuring the Torsional Properties in Metallic Bone Screws.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Ms. Amy H. Mommaerts
Manager, Regulatory Affairs
Pioneer Surgical Technology
375 River Park Circle
Marquette, Michigan 49855

Re: K003496
Trade Name: Cannulated Screw System
Regulatory Class: II
Product Codes: HTN and HWC
Dated: November 10, 2000
Received: November 13 2000

Dear Ms. Mommaerts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K003496

DEVICE NAME: Cannulated Screw

INDICATIONS FOR USE:

The Cannulated Screw System by Pioneer will be indicated for use in long and small bone fracture fixation, which may include the following:

1. Fractures of the tarsals and metatarsals;
2. Metatarsal and phalangeal osteotomies;
3. Fractures of the carpals and metacarpals;
4. Carpal and metacarpal arthrodesis;
5. Small fragments of the hand and wrist;
6. Ligament fixation as appropriate;
7. Sacroiliac joint disruptions;
8. Fractures of the distal femur and proximal tibia;
9. Intracapsular fractures of the hip;
10. Ankle arthrodesis; and
11. Pelvis and acetabulum fractures;

This system is not indicated for use in the spine. The Cannulated Screw System by Pioneer will be offered both sterile and non-sterile and is a single use device.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003496